

2018 Current Fiscal Year Report: Medical Devices Advisory Committee

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1. Department or Agency

Department of Health and Human Services

2. Fiscal Year

2018

3. Committee or Subcommittee

Medical Devices Advisory Committee

3b. GSA Committee No.

916

4. Is this New During Fiscal Year?

No

5. Current Charter

08/18/1999

6. Expected Renewal Date

7. Expected Term Date

8a. Was Terminated During Fiscal Year?

No

8b. Specific Termination Authority

8c. Actual Term Date

9. Agency Recommendation for Next Fiscal Year

Continue

10a. Legislation Req to Terminate?

Not Applicable

10b. Legislation Pending?

Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority

21 U.S.C. 360j(f)(3)

13. Effective Date

05/28/1976

14. Committee Type

Continuing

14c. Presidential?

No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports

No Reports for this Fiscal Year

17a. Open 6 Meetings and Dates 17b. Closed 0 17c. Partially Closed 0 Other Activities 0 17d. Total 6

Purpose	Start	End
On December 12, 2017, The Orthopedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee met to make recommendations and vote on information related to the Premarket Approval Application (PMA) for the Barricaid Anular Closer Device by Intrinsic Therapeutics. The Barricaid is intended to be implanted following a limited discectomy, to prevent re-herniation and the recurrence of pain or dysfunction. The panel deliberated on the study population, endplate lesions, and study endpoints. The panel voted 5/0/9 (yes/abstain/no) that the data shows a reasonable assurance that the device is safe for use in patients who meet the criteria specified; 12/1/1 (yes/abstain/no) that there is a reasonable assurance that the device is effective for use in patients who meet the criteria specified; and 5/1/8 (yes/abstain/no) that the benefits of the device outweigh the risks when used in patients who meet the criteria specified in the proposed indications.	12/12/2017	12/12/2017
On March 1, 2018, the Neurological Devices Panel met to discuss and made recommendations regarding the evaluation of clinical study data to support the risks and benefits of intracranial aneurysm treatment devices and factors that can affect clinical outcomes such as aneurysm morphology, size, and location in the neurovasculature. FDA also sought expert opinion on the scientific and clinical considerations relating to the clinical trial design that may be relevant to determining safety and effectiveness for these devices. The discussions resulted in recommendations on adverse events and endpoints, safety and patient demographics, effectiveness measures, aneurysm occlusion, patient follow up, retreatment, alternative imaging assessments, post approval studies, and labeling.	03/01/2018	03/01/2018

March 29, 2018: The Clinical Chemistry and Clinical Toxicology Devices Panel met to discuss, make recommendations, and vote on the Senseonics Eversense Continuous Glucose Monitoring (CGM) System PMA for continually measuring glucose levels in adults with diabetes. If approved, this prescription device, indicated as an adjunctive device to complement standard home blood glucose monitoring devices, will be the first fully implanted CGM sensor, the first to last for up to 90 days, and the first to use fluorescence to detect glucose. The Panel deliberated on clinical the study design; safety and effectiveness regarding modifications; drug interference; and the appropriate post-approval study for safety and effectiveness. The Panel voted unanimously—8/0/0 (yes/no/abstain)—that: 1) the data shows reasonable assurance that the device is safe for determining Insulin dose use in patients who meet the criteria specified in the proposed indications; 2) there is reasonable assurance that the device is effective for determining insulin dose in patients who meet the criteria specified in the proposed indications; and 3) the benefits of the device to determine insulin dose outweigh the risks for use in patients who meet the criteria specified in the proposed indications. On March 30, 2018, the Clinical Chemistry and Clinical Toxicology Devices Panel met to discuss the general use of blood glucose meters with capillary blood samples from patients throughout the hospital. FDA sought the panel's opinion on the benefits and risks of measuring capillary blood using blood glucose meters in patients receiving intensive medical intervention/therapy, and the considerations for CLIA waiver for this use. The panel felt that the benefits in patients receiving intensive medical intervention/therapy outweigh the risks. However, the panel also recognized that there are many clinical conditions (e.g., hypothermia, hypotension, shock, edema, etc.) in which capillary blood testing may be problematic. Potential risk mitigation strategies included increased training of medical personnel. The panel felt that a major issue was the quality of the capillary blood sample being assessed by the blood glucose meter rather than the blood glucose meter itself. As such, there was no consensus as to whether modifications of the current CLIA status of blood glucose meters in the hospitalized setting would address this issue. There were comments made both in favor and against maintaining a CLIA waiver for using glucose meters in patients receiving intensive medical intervention/therapy.

03/29/2018 - 03/30/2018

On June 12, 2018, the Circulatory System Devices Panel met to discuss, make recommendations, and vote on information related to the premarket approval application for the Cordis INCRAFT AAA Stent Graft System, intended for endovascular treatment of patients with infrarenal abdominal aortic aneurysms to exclude the aneurysm from blood flow. Based on data in the briefing materials and the meeting presentations, the Panel voted: 11/4/0 (Yes/No/Abstain) that considering the additional procedures needed to maintain effectiveness, there is reasonable assurance that the device is safe for use; 14/0/1 (Yes/No/Abstain) that there is reasonable assurance that the device is effective; 14/1/0 (Yes/No/Abstain) that the benefits of the device outweigh the risks.

06/12/2018 - 06/12/2018

On June 14, 2018, the Anesthesiology and Respiratory Therapy Devices Panel met to discuss, make recommendations, and vote on information related to the premarket approval application for PneumRx, Inc.'s PNEUMRX ELEVAIR Endobronchial Coils System, indicated for bronchoscopic placement of ELEVAIR Coils in patients with severe emphysema and severe hyperinflation to improve quality of life, lung function, and exercise capacity. Based on data in the briefing materials and meeting presentations, the Panel voted: 7/5/0 (Yes/No/Abstain) that considering the additional procedures needed to maintain effectiveness, the device is safe for use; 5/7/0 (Yes/No/Abstain) that there is reasonable assurance that the device is effective; 3/8/1 (Yes/No/Abstain) that the benefits of the device outweigh the risks.

06/14/2018 - 06/14/2018

On September 27, 2018, the Neurological Devices Panel met to discuss, make recommendations, and vote on Sequent Medical, Inc.'s premarket approval (PMA) application for the Woven Endobridge (WEB) Aneurysm Embolization System, which is intended to treat wide-neck intracranial aneurysms arising or located at a vessel bifurcation. The Panel voted on these items: (Yes/No/Abstain) that considering the additional procedures needed to maintain effectiveness, there is reasonable assurance that the device is safe for use; (Yes/No/Abstain) that there is reasonable assurance that the device is effective; (Yes/No/Abstain) that the benefits of the device outweigh the risks.

09/27/2018 - 09/27/2018

Number of Committee Meetings Listed: 6

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	\$26,192.00	\$41,013.00
18a(2). Personnel Pmts to Federal Members	\$3,094.00	\$3,828.00
18a(3). Personnel Pmts to Federal Staff	\$2,623,274.00	\$2,464,779.00
18a(4). Personnel Pmts to Non-Member Consultants	\$53,899.00	\$78,746.00

18b(1). Travel and Per Diem to Non-Federal Members	\$32,403.00	\$48,906.00
18b(2). Travel and Per Diem to Federal Members	\$253.00	\$445.00
18b(3). Travel and Per Diem to Federal Staff	\$0.00	\$0.00
18b(4). Travel and Per Diem to Non-member Consultants	\$63,140.00	\$93,402.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	\$713,413.00	\$725,287.00
18d. Total	\$3,515,668.00	\$3,456,406.00
19. Federal Staff Support Years (FTE)	19.05	15.75

20a. How does the Committee accomplish its purpose?

The Medical Devices Advisory Committee provides advice to FDA on the safety and effectiveness of marketed and investigational devices, the classification of devices into one of three regulatory categories, the possible risks to health associated with the use of devices, the formulation of product development protocols, the review of premarket approval applications, and the content of guidelines or guidance documents designed to improve the interaction between the Agency and sponsors of medical devices. This committee consists of 18 advisory panels: 17 are divided according to medical specialties and one is a dispute resolution panel. In FY 2018, six meetings were held.

20b. How does the Committee balance its membership?

Members are drawn from the nation's top academicians, clinicians and researchers and they provide expertise in a full range of medical specialties. These medical specialties include anesthesiology, cardiac catheterization and electrophysiology, cardiology, cardiothoracic and vascular surgery, radiation physics, radiotherapy, mammography radiology, biomaterials, cytopathology, molecular genetics, clinical toxicology, chemical engineering, orthopaedic surgery, biostatistics, gastroenterology, nephrology, esophageal disorders, trauma, burn and wound plastic surgery, surgical oncology, reconstructive plastic surgery, periodontology, biochemistry, immunology, oral and maxillofacial surgery, vision sciences, corneal disease, ophthalmological surgery, perinatology, reproductive endocrinology, obstetrics and gynecology, neurology, cerebrovascular surgery, interventional neuroradiology, neurological surgery, neurological disorders and stroke, and pediatric surgery. There is at least one consumer and industry representative per panel and while they do not vote, they do provide viewpoints from their respective constituencies. Qualified females and minorities are encouraged to apply for vacancies.

20c. How frequent and relevant are the Committee Meetings?

The Committee had six meetings in FY 2018 and tentatively plans 12 meetings for the coming year to address new technologies coming to market and to address questions that may arise about existing technologies. The scope and depth of expertise that Committee

members possess is not always available within the Agency; therefore, the Panel meetings provide a source of expert advice to the Agency on premarket review decisions, postmarket issues, classification and reclassification decisions, early discussion of study designs, and guidance documents. During FY 2018, Panels convened to discuss and make recommendations on the following premarket approval applications (PMAs): Intrinsic Therapeutics' Barricaid® Annular Closure Device to prevent reherniation of the spinal disc; Cordis' Incraft AAA Stent Graft System for abdominal aortic aneurysms; PneumoRx's Elevair Endobronchial Coil System, a first-of-a-kind lung reduction coil to treat emphysema; Senseonics's Eversense Continuous Glucose Monitoring System used in the treatment of diabetes; and Sequent Medical's Woven Endobridge (WEB) Embolization Device to treat intracranial aneurysm. The Panel also met to discuss clinical trial design and study data requirements to support the safety and effectiveness of intracranial aneurysm treatment devices. Additionally, the Panel met to discuss and make recommendations on measuring blood glucose in hospital patients using blood glucose meters. During a joint meeting with the Blood Products Advisory Committee, the Microbiology Devices Panel discussed and made recommendations for the reclassification from Class III to Class II of Hepatitis C Virus Tests used as aids in diagnosing HCV Infection and/or managing infected patients.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

Committee members are selected from academia, research, and/or clinical practice. The advice they provide helps decisions stand up under public scrutiny and offers credibility to the regulatory process. The goals of the committee can only be met using these alternate means to obtain sound advice.

20e. Why is it necessary to close and/or partially closed committee meetings?

N/A

21. Remarks

The Panels of this Committee meet as needed, rather than on a regular basis; therefore, some Panels did not meet during FY 2018 and have no reporting requirements. For the Panels that did not meet, considerable time was devoted to reappointing current members, maintaining associated records for these activities, and streamlining paper processes within FDA. In addition, time was spent in the routine care and maintenance of the committee: the development of a financial report for this website; updating the roster and number of vacancies on our website; completing the annual ethics report; reviewing financial disclosures of current members and providing ethics training. In FY 2018 the Committee met in joint session with another committee, but was not the Lead Committee.

March 22, 2018: The Blood Products Advisory Committee was the lead in a joint meeting with the Microbiology Devices Panel of the Medical Devices Advisory Committee. The meeting was convened to discuss and make recommendations for the reclassification from Class III (PMA) to Class II (510(k)) with special controls) of Hepatitis C Virus (HCV) Antibody Tests and HCV Nucleic Acid Based Tests used as aids in diagnosing HCV Infection and/or managing HCV-infected patients. Panelists: • recommended down classification of the tests to Class II, • agreed with the development of special controls as presented by the FDA and recommended special controls to address possible use of a lower performing predicate device • encouraged sponsors to consider gathering more data from pediatric populations and subpopulations, • agreed with the FDA proposed performance criteria to mitigate risks, • felt that future rapid point of care test technologies may require modified performance criteria, and opined that no currently marketed devices should be removed if they did not meet higher performance criteria that might be included in special controls for new devices. FDA agreed • that performing new device benefit risk analysis based on a device's specific intended use may allow flexibility for different performance criteria with devices significantly different than those currently marketed, • that FDA could require Annual Reporting in the special controls if it was felt necessary to assure safe and effective use.

Designated Federal Officer

James P. Swink Director, Medical Devices Advisory Committee

Committee Members	Start	End	Occupation	Member Designation
Abraham, Roshini	04/01/2015	02/28/2019	Prof. of Med. & Laboratory Med. & Pathology, Rochester, MN	Special Government Employee (SGE) Member
Adcock (Funk), Dorothy	03/01/2017	02/28/2021	Medical/Laboratory Director, Esoterix Coagulation, Englewood, CO	Special Government Employee (SGE) Member
Afifi, Abdelmonem	01/01/2017	12/31/2020	Prof., Biostatistics & Dean Emeritus, Dept. of Biostatistics, School of Public Health, UCLA, Los Angeles, CA	Special Government Employee (SGE) Member
Agazie, Sandra	02/10/2014	12/31/2017	Admin. Director, Sanzie Healthcare Serv. Inc., Fayetteville, GA	Special Government Employee (SGE) Member
Alexander, Barbara	09/29/2017	02/28/2020	Professor of Medicine, Duke Univ. Medical Center, Durham, NC	Special Government Employee (SGE) Member
Amrami, Kimberly	09/01/2017	08/31/2021	Consultant in Radiology, Dept. of Radiology/Mayo Clinic, Rochester, MN	Special Government Employee (SGE) Member
Baxter, William	09/13/2017	11/30/2020	Vice. Pres. and Co-Owner, TN Interventional & Imaging Assoc., Chattanooga, TN	Special Government Employee (SGE) Member
Beavis, Kathleen	07/22/2014	02/28/2018	Director, Univ. of Chicago, Microbiology Virology Laboratories, Chicago, IL	Special Government Employee (SGE) Member

Birdsong, George	03/01/2017	02/28/2020	Dir., Anatomic Pathology, Grady Memorial Hosp., Atlanta, GA	Special Government Employee (SGE) Member
Bowers, Larry	07/31/2015	02/28/2018	Chief Science Office, U.S. Anti-Doping Agency, Colorado Springs, CO	Special Government Employee (SGE) Member
Bracco, Daniel	01/01/2014	12/31/2017	Head of Clinical and Regulatory, Roche Diagnostics Hematology, Westborough, MA	Representative Member
Branson, Richard	02/05/2015	11/30/2018	Prof. of Surgery, Dir. of Clinical Research, Univ. of Cincinnati Med. Ctr, Cincinnati, OH	Special Government Employee (SGE) Member
Braswell, Laura	11/29/2017	10/31/2021	Buckhead Periodontics, Atlanta, GA	Special Government Employee (SGE) Member
Brazier, Rita	03/01/2017	02/28/2021	Professor and Dir. of Hematopathology Div., Oregon Health & Sciences Univ., Portland, OR	Special Government Employee (SGE) Member
Bremer, Andrew	04/25/2017	02/28/2021	Med. Officer & Program Dir., NIH, Bethesda, MD	Regular Government Employee (RGE) Member
Brietzke, Scott	03/23/2017	10/31/2020	Dir. Pediatric Otolaryngology & Adult Sleep Surgery, Walter Reed Natl. Mil. Med. Ctr., Bethesda, MD	Regular Government Employee (RGE) Member
Brindis, Ralph	08/24/2017	06/30/2021	Clinical Professor of Medicine, Univ. of California, San Francisco	Special Government Employee (SGE) Member
Brown, Debera	12/21/2017	11/30/2021	Principal, D. Brown Consulting Services LLC, Palo Alto, CA	Representative Member
Brummert, Rachel	01/19/2017	08/31/2020	Consumer Representative; President, Quinolone Vigilance, Charlotte, NC	Special Government Employee (SGE) Member
Burke, Karen	05/19/2016	08/31/2019	Dermatologist, Dermatology Office of Karen Burke, New York, NY	Special Government Employee (SGE) Member
Burr, Robert	01/01/2015	12/31/2018	Pres. & Medical Dir., Battelle Memorial Inst. in Columbus, Ohio	Special Government Employee (SGE) Member
Bush, Lee	09/29/2017	01/31/2021	Regulatory Affairs Manager, GE Healthcare, Waukesha, WI	Representative Member
Caliendo, Angela	07/22/2014	02/28/2018	Chief, Div. of General Internal Med., Rhode Island Hosp., Providence, RI	Special Government Employee (SGE) Member
Cassiere, Hugh	03/30/2018	11/30/2022	Associate Prof. Medicine and Assoc. Prof. of Cardiovascular and Thoracic Surgery, Hofstra Northwell School of Medicine, Hempstead, NY	Special Government Employee (SGE) Member
Caton, Jack	12/12/2014	10/31/2018	Professor & Chair, Univ. of Rochester, Div. of Periodontology	Special Government Employee (SGE) Member
Chadwick, David	05/22/2017	10/31/2020	Dir., Regulatory Affairs/Regulatory Science, Cook Medical, Bloomington, IN	Representative Member
Chandrasekhar, Sujana	02/05/2018	10/31/2021	Clinical Associate Professor of Otolaryngology, Mount Sinai School of Medicine, New York, NY	Special Government Employee (SGE) Member
Chappell, Richard	01/22/2016	01/31/2019	Prof., Dept. of Biostatistics and Med., Univ. of Wisc. Madison Med. Schl., Madison, WI	Special Government Employee (SGE) Member

Cheung, Steven	11/01/2013	10/31/2017	Prof., Head & Neck Surgery, Univ. of California, San Francisco, CA	Special Government Employee (SGE) Member
Cigarroa, Joaquin	07/01/2015	06/30/2019	Assoc. Chief of Clinical Cardiology, Knight Cardiovascular Inst., Portland, OR	Special Government Employee (SGE) Member
Coldwell, Douglas	02/01/2015	01/31/2019	Prof. of Radiology, Univ. of Louisville, Louisville, KY	Special Government Employee (SGE) Member
Connor, Jason	12/01/2013	11/30/2017	Statistical Scientist, Berry Consultants, Orlando, FL	Special Government Employee (SGE) Member
D'Orsi, Carl	01/30/2015	01/31/2018	Prof. of Radiology & Hematology & Oncology, Emory Univ. Hosp., Atlanta, GA	Special Government Employee (SGE) Member
Dahr, Sami	01/31/2017	10/31/2020	Vitreoretinal Surgeon, Retina Ctr. of OK, Oklahoma City, OK	Special Government Employee (SGE) Member
Daigle, Patricia	10/01/2014	09/30/2019	Consumer Representative: Family Nurse Practice, Louisiana State Med. Ctr., Lafayette, LA	Representative Member
Davis, Ann	02/01/2015	01/31/2019	Hoover, AL 35226	Special Government Employee (SGE) Member
Desjardins, Philip	10/01/2017	09/30/2021	Vice President, Regulatory Affairs, Policy and Intelligence Medical Devices Diagnostics, Johnson and Johnson, New Brunswick, NJ	Representative Member
Dodd, Lori	09/29/2017	02/28/2021	Mathematical Statistician, National Institutes of Health/NIAID, Div., Clinical Research, Rockville, MD	Regular Government Employee (RGE) Member
Domino, Karen	02/05/2015	11/30/2017	Prof. of Anesthesiology, Univ. of WA School of Med., Seattle, WA	Special Government Employee (SGE) Member
Dorsey, Earl	12/14/2017	11/30/2021	Prof. of Neurology and Medical Dir., Telemedicine, Univ. of Rochester, Rochester, NY	Special Government Employee (SGE) Member
Duff, Kevin	09/13/2017	11/30/2020	Prof. of Neurology, Univ. of Utah, Salt Lake City, UT	Special Government Employee (SGE) Member
Durgin, Robert	12/24/2015	10/31/2018	Vice Pres., Regulatory Affairs & Quality Assurance, KaVo KerrGroup/Danaher Corp., Charlotte, NC	Representative Member
Edwards, Veverly	12/14/2017	11/30/2021	Consumer Representative: Affiliate Broker, First National Realty, Memphis, TN	Representative Member
Elser, Denise	01/23/2015	01/31/2018	Medical Dir., Womans Health Inst. of Illinois, LTD., Oak Lawn, IL	Special Government Employee (SGE) Member
Escobar, Luis	02/10/2014	05/31/2021	Medical Dir., Medical Genetics and Neurodevelopmental Ctr., St. Vincent Hospital, Indianapolis, IN	Special Government Employee (SGE) Member
Espey, Eve	05/17/2017	01/31/2021	Div. Chief, Univ. of New Mexico, Albuquerque, NM	Special Government Employee (SGE) Member
Evans, Scott	02/01/2016	08/31/2019	Director, Biostatistics Center George Washington Univ., Washington, DC	Special Government Employee (SGE) Member
Falcone, Tommaso	02/01/2015	01/31/2018	Prof. & Chairman, Dept. of Obstetrics & Gynecology, Cleveland Clinic Foundation, Cleveland, OH	Special Government Employee (SGE) Member

Felix, Juan	04/01/2015	02/28/2022	Dir., Clinical pathology and Ob/Gyn Dept. of Pathology, Keck School of Medicine, Univ. of Southern, California, Los Angeles, CA	Special Government Employee (SGE) Member
Fields, Ryan	11/29/2017	08/31/2020	Associate Prof. of Surgery, Dept. of Surgery, Barnes-Jewis, Washington Univ., School of Medicine., St. Louis, MO	Special Government Employee (SGE) Member
Finnegan, Maureen	09/01/2014	08/31/2022	Assoc. Prof., Univ. of TX Southwestern Med. Center, Dallas, TX	Special Government Employee (SGE) Member
Frankel, Naftali	12/10/2015	04/29/2018	CONSUMER REPRESENTATIVE: Research Fellow, Yew Gardens, NY	Special Government Employee (SGE) Member
Frankel, Naftali	12/10/2015	04/28/2018	Unknown	Representative Member
Freed, Brian	08/22/2017	02/28/2021	Executive Dir., Clinimmune Labs, Auroa, CO	Special Government Employee (SGE) Member
Gelato, Marie	04/25/2017	02/28/2021	Prof. of Medicine, Dept of Medicine, Health Sci. Ctr., Stony Brook, NY	Special Government Employee (SGE) Member
Gilbert, Jeremy	09/01/2017	08/31/2021	Adjunct Prof., Dept. of Orthopaedic Surgery, Med. Univ. of S. Carolina, Charleston, SC	Special Government Employee (SGE) Member
Goldberger, Bruce	03/01/2018	02/28/2022	Prof. and Dir. of Toxicology, Dept. of Pathology, Univ. FL, Gainesville, FL	Special Government Employee (SGE) Member
Grunberger, George	03/01/2018	02/28/2022	Chairman, Grunberger Diabetes Inst., Bloomfield Hills, MI	Special Government Employee (SGE) Member
Gualtieri, Lisa	01/01/2016	12/31/2019	Asst. Prof. Dept of Public Health, Tufts Univ. of Med., Boston, MA	Special Government Employee (SGE) Member
Halabi, Susan	09/01/2016	08/31/2019	Assoc. Prof. Duke Univ., Durham NC	Special Government Employee (SGE) Member
Hamilton, Robert	03/01/2016	02/28/2020	Profesor of Medicine and Pathology; Johns Hopkins Univ. School of Medicine, Baltimore, MD	Special Government Employee (SGE) Member
Hays, Ronald	03/20/2017	10/31/2020	Prof. Medicine/Gen Internal Med & Health, UCLA, Los Angeles, CA	Special Government Employee (SGE) Member
Hedayat, Samad	01/30/2015	01/31/2020	UIC Distinguished Professor, Dept. of Math, Statistics and Computer Science, Univ. of Illinois at Chicago, Chicago, IL	Special Government Employee (SGE) Member
Higashida, Randall	12/01/2015	11/30/2019	Chief, Div. Interventional Neurovascular Radiology, Univ. of California, San Francisco	Special Government Employee (SGE) Member
Hillis, Stephen	02/01/2015	01/31/2019	Research Prof., Univ. of Iowa, Iowa City, IA	Special Government Employee (SGE) Member
Hirsch, Barry	12/24/2014	10/31/2018	Director, Dept. of Otolaryngology, Univ. of Pittsburgh, Eye & Ear Inst., Pittsburgh, PA	Special Government Employee (SGE) Member
Hirshfeld, Jr., John	01/31/2018	09/30/2020	Professor of Medicine, Perelman School of Medicine, Univ. of Pennsylvania School of Medicine, Philadelphia, PA	Special Government Employee (SGE) Member

Hoofnagle, Andrew	03/01/2016	02/28/2020	Associate Prof. of Laboratory Medicine; Univ. of Washington, Seattle, WA	Special Government Employee (SGE) Member
Horvath, Keith	07/01/2016	06/30/2020	Director, Cardiothoracic Surgery Res. Br., Nat'l Heart, Lung and Blood Inst/NIH, Bethesda, MD	Special Government Employee (SGE) Member
Huang, Andrew	11/01/2014	10/31/2018	Professor, Dept. of Ophthalmology & Visual Sciences, Washington Univ. School of Medicine, St. Louis, MO	Special Government Employee (SGE) Member
Hunt, Kelly	01/23/2015	08/31/2018	Prof. Chief, Dept. of Surgical Oncology, MD Anderson Cancer Ctr, Houston, TX	Special Government Employee (SGE) Member
Isaacson, Keith	09/10/2018	01/31/2022	Dir. of Min. Invasive Surgery, Newton Wellesley Hosp., Newton, MA	Special Government Employee (SGE) Member
Ishiyama, Akira	12/24/2014	10/31/2018	Assoc. Prof., Dept. of Otolaryngology-Head & Neck Surgery, UCLA, Los Angeles, CA	Special Government Employee (SGE) Member
Janik, Grace	09/10/2018	01/31/2021	Associate Dir., Medical College of Wisconsin, Columbia St. Marys Campus, Milwaukee, WI	Special Government Employee (SGE) Member
Janosky, Janine	10/01/2017	09/30/2021	Dean College of Education, Health and Human Services, Univ. of Michigan-Dearborn, Dearborn, MI	Special Government Employee (SGE) Member
Jarvis, Gary	08/31/2018	06/30/2022	VP Technology/Regulatory Clinical and Medical Affairs, Alfa Medical, Eden Prairie, MN	Representative Member
Jarvis, William	01/01/2015	12/31/2018	Pres. & Medical Consultant, Jason & Jarvis Assoc., Hilton Head Island, SC	Special Government Employee (SGE) Member
Jeffcoat, Marjorie	11/05/2013	10/31/2017	Dean, School of Medicine, Univ. of Pennsylvania, Philadelphia, PA	Special Government Employee (SGE) Member
Jeng, Bennie	11/01/2014	10/31/2018	Chair & Prof., Dept. of Ophthalmology & Visual Sciences, Univ. of MD, Baltimore, MD	Special Government Employee (SGE) Member
Jensen, Mary	12/01/2015	11/30/2019	Dir., Interventional Neuro., Univ. of VA Health System, Charlottesville, VA	Special Government Employee (SGE) Member
Jessup, John	03/01/2016	12/10/2017	Scientific Director, Inova Dwight & Martha Schar Cancer Inst., Falls Church, VA	Special Government Employee (SGE) Member
Jiang, Yulei	02/01/2015	01/31/2019	Assoc. Prof., Univ. of Chicago, Chicago, IL	Special Government Employee (SGE) Member
Kalota, Susan	01/01/2014	12/31/2017	Urologist, Urologic Associates of Southern AZ, Tuscon, AZ	Special Government Employee (SGE) Member
Kandzari, David	07/01/2015	06/30/2019	Dir. Interventional Cardiology, Piedmont Heart Inst., Atlanta, GA	Special Government Employee (SGE) Member
Karon, Bradley	04/09/2014	02/28/2022	Prof. of Laboratory Medicine and Pathology, Mayo Clinic, Rochester, MN	Special Government Employee (SGE) Member
Kawasaki, Arthur	05/31/2017	05/31/2021	Sr. Dir., Canon BioMedical, Inc., Rockville, MD	Representative Member
Kielb, Stephanie	04/20/2018	12/31/2022	Assoc. Prof. of Urology, Dept. of Urology, Northwestern Univ Feinberg School of Medicine	Special Government Employee (SGE) Member

Kimberlin, David	09/29/2017	02/28/2021	Professor, Univ. of Alabama at Birmingham, AL	Special Government Employee (SGE) Member
Kimes, David	04/01/2015	02/28/2019	Industry Representative, Divisional Vice Pres., Global Quality Assurance, Abbott Park, IL	Representative Member
Kirsch, Jeffrey	12/01/2015	11/30/2019	Prof and Chair, Dept. of Anesthesiology and Perioperative Medicine, Oregon Health and Science	Special Government Employee (SGE) Member
Klein, Ulrich	11/01/2015	10/31/2019	Chairperson, Dept. of Pediatric Dentistry, Univ. of CO Denver Schl of Dental Med and Children's Hosp of CO	Special Government Employee (SGE) Member
Kline, Andrea	09/30/2015	11/30/2018	Pediatric Nurse Practitioner, Detroit, MI	Special Government Employee (SGE) Member
Kochman, Michael	09/30/2016	12/31/2019	Assoc. Prof. of Medicine, Hosp. of the Univ. of PA., Philadelphia, PA	Special Government Employee (SGE) Member
Kroll, Martin	07/31/2015	12/24/2017	Corporate Clinical Pathology Dir., Quest Diagnostics, Madison, NJ	Special Government Employee (SGE) Member
Krupinski, Elizabeth	01/30/2015	01/31/2018	Prof. of Radiology & Hematology & Oncology, Univ. of Arizona, Tucson, AZ	Special Government Employee (SGE) Member
Kwong, Tai	07/31/2015	02/28/2018	Directed Automated Lab, Strong Mem. Hosp., Rochester, NY	Special Government Employee (SGE) Member
Lakos, Gabriella	04/25/2017	02/28/2020	Sr. Assoc. Medical Dir., Abbott Laboratories, Santa Clara, CA	Representative Member
Lange, Richard	07/01/2018	06/30/2022	President, Tech Univ. Health Sciences Ctr. El Paso, El Paso, TX	Special Government Employee (SGE) Member
Leitch, Ann	11/29/2017	08/31/2021	Prof., Dept. of Surgery, UT. SW Medical School/Center, Dallas, TX	Special Government Employee (SGE) Member
Lettieri, Christopher	02/05/2015	11/30/2017	Program Dir., Sleep Medicine, Walter Reed National Mil. Med. Ctr, Bethesda, MD	Regular Government Employee (RGE) Member
Lew, Susie	01/01/2014	12/31/2017	Prof. of Medicine, Dir. of Clinical Services, George Washington Med. Ctr., Washington, DC	Special Government Employee (SGE) Member
Lewis, Jr., Frank	11/29/2017	08/31/2021	Exec. Dir., American Board of Surgery, Philadelphia, PA	Special Government Employee (SGE) Member
Lison, Wyatt	03/23/2017	05/31/2021	Consumer Representative; Partner, Feintsein Doyle Payne & Kravec, LLC, Pittsburgh, PA	Special Government Employee (SGE) Member
Marshall, Milton	11/22/2016	10/31/2020	Marshall & Associates, Houston, TX	Special Government Employee (SGE) Member
McGuire, Michael	12/12/2014	10/31/2018	Clinical Assistant Professor, University of Texas Dental Branch, Houston, TX	Special Government Employee (SGE) Member
McLeod, Stephen	11/01/2013	10/31/2017	Chairman, Dept. of Ophthalmology, Prof. of Clinical Ophthalmology, Univ. of CA, San Francisco, San Francisco, CA	Special Government Employee (SGE) Member
Miller, Michael	11/29/2017	08/31/2021	Prof. & Chair, Dept. of Plastic Surg., the Ohio State Univ., Columbus. OH	Special Government Employee (SGE) Member

Moore, Thomas	09/29/2017	02/28/2020	Clinical Professor of Medicine, Univ. of Kansas School of Medicine, Wichita Campus, Wichita, KS	Special Government Employee (SGE) Member
Morgan, Charity	01/01/2015	12/31/2018	Asst. Professor, Univ. of Alabama at Birmingham, Birmingham, AL	Special Government Employee (SGE) Member
Moxey-Mims, Marva	04/20/2018	12/31/2022	Chief of Pediatric Nephrology, Children's National Health System, Washington, DC	Special Government Employee (SGE) Member
Myers, Deborah	01/16/2015	01/31/2018	Dir., Div of Urogynecology & Reconstructive Pelvic, Women & Infants Hosp. of RI, Providence, RI	Special Government Employee (SGE) Member
Nathan, Steven	02/05/2015	11/30/2017	Medical Dir., Adv. Lung Disease & Lung Transplant Program, Inova Fairfax Hosp., Falls Church, VA	Special Government Employee (SGE) Member
Newman, Clarke	03/20/2017	10/31/2020	Consumer Representative; Dir. of Optometry, Plaza Vision Ctr., Dallas, TX	Special Government Employee (SGE) Member
Nishikawa, Robert	09/27/2017	01/31/2021	Professor, Imaging Research Div., Univ. of Pittsburgh Dept. of Radiology, Pittsburgh, PA	Special Government Employee (SGE) Member
Norback, Diane	03/01/2017	02/28/2020	Assoc. Professor, Univ. of WI Hosp., Madison, WI	Special Government Employee (SGE) Member
Norton, Susan	11/01/2013	10/31/2020	Chief, Research and Clinical Audiology, Seattle Children's Hospital, Seattle, WA	Special Government Employee (SGE) Member
Novy, Brian	08/30/2016	10/31/2019	Consumer Representative; Dir. of Practice Improvement, DentaQuest Institute, Westborough, MA	Special Government Employee (SGE) Member
Page, Richard	09/09/2014	06/30/2018	Chair, Dept. of Med., Univ. of Wisconsin School of Medicine and Public Health, Madison, WI	Special Government Employee (SGE) Member
Patton, Kristen	07/01/2015	06/30/2019	Assoc. Prof., Univ. of Washington, Seattle, WA	Special Government Employee (SGE) Member
Pawelski, Lynn	01/19/2017	08/31/2020	Vice President/Global Regulatory Affairs, Baxter Healthcare Corp., Deerfield, IL	Representative Member
Petersen, Carolyn	12/01/2017	11/30/2021	Consumer Representative: Web Communications Consultant, Mayo Clinic Global Business Solutions, Rochester, MN	Representative Member
Pfleger, Michael	11/01/2013	10/31/2017	VP, Head of External Affairs & Regulatory Policy, Alcon, Inc., Ft. Worth, TX	Representative Member
Pien, Grace	02/05/2015	11/30/2018	Asst. Prof. of Medicine, Johns Hopkins School. of Medicine., Baltimore, MD	Special Government Employee (SGE) Member
Pilitsis, Julie	12/14/2017	11/30/2020	Chair, Dept., Neuroscience and Experimental Therapeutics, Albany Med. College, Albany, NY	Special Government Employee (SGE) Member
Press, Richard	09/09/2014	05/31/2018	Med. Director, Dept. of Pathology, OR. Health & Sci. Univ., Portland, OR	Special Government Employee (SGE) Member
Przygodzki, Ronald	06/01/2017	05/31/2020	Acting Dir., Biomedical Lab. R & D, Dept. of Veterans Affairs, Washington, DC	Regular Government Employee (RGE) Member
Rao, Rajkumar	02/09/2010	08/31/2019	Chair, Dept. of Orthopaedic Surgery, George Washington Univ. Washington, DC	Special Government Employee (SGE) Member

Remaley, Alan	07/31/2015	02/28/2019	Director, Immunoassay Sec., NIH, Rockville, MD	Regular Government Employee (RGE) Member
Rendell, Marc	02/20/2018	02/28/2020	Medical Director, Rose Salter Medical Research Foundation, Newport Coast CA	Special Government Employee (SGE) Member
Reppas, John	12/01/2013	11/30/2017	Dir. of Public Policy, Neurotechnology Industry Organization, San Francisco, CA	Representative Member
Reynolds, Mark	11/05/2013	10/31/2021	Prof. & Chair, Dept of Periodontics, Univ. of Maryland School of Dentistry, Baltimore, MD	Special Government Employee (SGE) Member
Rogers, Rebecca	02/01/2016	01/31/2020	Associate Chair Department of Women's Health University of Texas at Austin 1301 West 38th Street Suite 705 Austin Texas	Special Government Employee (SGE) Member
Rosenbloom, Arlan	07/31/2015	11/17/2017	Adjunct Distinguish Service	Special Government Employee (SGE) Member
Rue, Karen	01/22/2016	01/31/2019	Consumer Representative; Dir., Acadiana Off. of Griswald Special Care, Lafayette, LA	Special Government Employee (SGE) Member
Sayeed, Yusef	12/30/2015	12/10/2017	Consumer Representative; Physician, WV Univ, Morgantown, WV	Special Government Employee (SGE) Member
Schneider, Erasmus	09/09/2014	05/31/2018	Director, Div. of Translational Med., NY State Dept. of Health, Albany, NY	Special Government Employee (SGE) Member
Schwaitzberg, Steven	01/01/2017	12/31/2020	Prof. and Chairman, Dept of Surgery, Univ of Buffalo Sch of Med and Bio Science, Buffalo, NY	Special Government Employee (SGE) Member
Simon, Thomas	10/23/2014	02/28/2018	Exec. Director, Interfaith Companion & Ride Express, Decatur, GA	Representative Member
Singh, Kuldev	11/01/2013	10/31/2017	Prof. of Ophthalmology & Dir. of Glaucoma Service, Stanford Univ. School of Med., Palo Alto, CA	Special Government Employee (SGE) Member
Skates, Steven	06/01/2015	05/31/2019	Assoc. Professor of Medicine, Massachusetts General Hospital Biostatistics Center, Boston, MA	Special Government Employee (SGE) Member
Smith, Harvey	09/30/2016	08/31/2020	Assistant Professor of Neurosurgery, Univ. of Pennsylvania School of Medicine	Special Government Employee (SGE) Member
Spring, Bradford	09/29/2017	02/28/2021	Vice President, Regulatory Affairs, Becton Dickinson & Company, Sparks, MD	Representative Member
Starowicz, Sharon	02/21/2017	08/31/2020	Johnson & Johnson, Rayham, MA	Representative Member
Stetler-Stevenson, Maryalice	08/22/2017	02/28/2021	Chief, Flow Cytometry Lab., NIH, Bethesda, MD	Regular Government Employee (RGE) Member
Stockwell, Jana	10/01/2014	09/30/2018	Director, Clinical Care Medicine, Emory Univ. Schl. of Med., Atlanta, GA	Special Government Employee (SGE) Member
Sully Sayeed, Keziah (Kate)	01/01/2017	12/31/2020	Consumer Representative; Interventional Pain Fellow, Deuk Spine Ctr., Melbourne, FL	Special Government Employee (SGE) Member
Suzuki, Jon	12/12/2014	10/31/2017	Assoc. Dean of Graduate Education, Research, Intl. Affiliates, Temple Univ., Philadelphia, PA	Special Government Employee (SGE) Member

Terris, David	12/24/2014	10/31/2018	Prof. & Chair, Dept. of Otolaryngology Head & Neck Surgery, Medial College of Georgia, Augusta, GA	Special Government Employee (SGE) Member
Timberlake, Sharon	09/04/2018	01/31/2022	Sharon Timberlake Consulting LLC, Wayland, MA	Representative Member
Vaughan, Jr., William	01/30/2015	01/31/2018	Consumer Representative: Clinical Trials, Falls Church, VA	Special Government Employee (SGE) Member
Vetrovec, George	07/01/2016	06/30/2020	Prof. Emeritus, VA Commonwealth Univ., Richmond, VA	Special Government Employee (SGE) Member
Wang, Helen	04/01/2015	01/10/2018	Medical Director of Cytopathology, Boston, MA	Special Government Employee (SGE) Member
Wang, Hom-Lay	11/29/2017	10/31/2021	Prof. & Dir., Graduate Periodontics/Prevention/Geriatrics, School of Dentistry, Univ. of Michigan, Ann Arbor, MI	Special Government Employee (SGE) Member
Weiss, Jayne	11/01/2014	10/31/2018	Prof. & Chair, Dept. of Ophthalmology, Louisiana State Univ. Health Sciences Ctr., New Orleans, LA	Special Government Employee (SGE) Member
Woolf, Alan	02/10/2014	12/31/2017	Director, Pediatric Environmental Health Ctr., Boston, MA	Special Government Employee (SGE) Member
Wreh, Elijah	12/01/2017	11/30/2021	Regulatory Affairs Manager, Invacare Corp., Elyria, OH	Representative Member
Wyne, Kathleen	02/20/2018	02/28/2021	Director, Adult Type 1 Diabetes Prog., Ohio State Univ., Wexner Med. Ctr., Columbus, OH	Special Government Employee (SGE) Member
Yang, Lynda	12/01/2016	08/31/2020	Neurosurgeon, Univ of Michigan, Ann Arbor, MI	Special Government Employee (SGE) Member
Yarmus, Lonny	03/30/2018	11/30/2021	Assoc. Prof. of Medicine and Oncology/Dir. Div., Pulmonary and Critical Care Medicine, Johns Hopkins Univ. Schol of Med., Baltimore, MD	Special Government Employee (SGE) Member
Yueh, Bevan	11/01/2013	10/31/2020	Prof. & Chair, Dept of Otolaryngology, Univ. of Minnesota, Minneapolis, MN	Special Government Employee (SGE) Member
Yusen, Roger	08/28/2017	12/31/2019	Assoc. Prof. of Medicine, Washington Univ. Schl. of Medicine, St. Louis, MO	Special Government Employee (SGE) Member
Zehnbauer, Barbara	06/01/2015	05/31/2019	Sr. Service Fellow & Branch Chief, CDC, Atlanta, GA	Regular Government Employee (RGE) Member
Zhang, Lanjing	03/01/2017	02/28/2021	Consumer Representative; Clinical Asst. Prof., Pathology Dept, Ruthology Robert Wood Johnson, Med Schl, Westfield, NJ	Special Government Employee (SGE) Member
van Berkel, Victor	08/28/2017	12/31/2020	Assoc. Prof., Univ. of Louisville Schl. of Medicine, Louisville, KY	Special Government Employee (SGE) Member

Number of Committee Members Listed: 164

Narrative Description

FDA's strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of

the global supply chain; strengthen compliance and enforcement activities to support public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Panels (of the Medical Devices Advisory Committee (MDAC)) of the Center for Devices and Radiological Health (CDRH) Advisory Committee organized under 513(b) of the Federal Food, Drug and Cosmetic Act supports the FDA mission and strategic plan by providing independent expert scientific advice on the safety and efficacy of medical devices and radiation emitting products. The Panels also offer an opportunity for public input on all the issues that attend the introduction of new medical devices.

What are the most significant program outcomes associated with this committee?

Checked if Applies

- | | |
|---|-------------------------------------|
| Improvements to health or safety | <input checked="" type="checkbox"/> |
| Trust in government | <input checked="" type="checkbox"/> |
| Major policy changes | <input checked="" type="checkbox"/> |
| Advance in scientific research | <input checked="" type="checkbox"/> |
| Effective grant making | <input type="checkbox"/> |
| Improved service delivery | <input type="checkbox"/> |
| Increased customer satisfaction | <input checked="" type="checkbox"/> |
| Implementation of laws or regulatory requirements | <input checked="" type="checkbox"/> |
| Other | <input type="checkbox"/> |

Outcome Comments

NA

What are the cost savings associated with this committee?

Checked if Applies

- | | |
|----------------------------|-------------------------------------|
| None | <input type="checkbox"/> |
| Unable to Determine | <input checked="" type="checkbox"/> |
| Under \$100,000 | <input type="checkbox"/> |
| \$100,000 - \$500,000 | <input type="checkbox"/> |
| \$500,001 - \$1,000,000 | <input type="checkbox"/> |
| \$1,000,001 - \$5,000,000 | <input type="checkbox"/> |
| \$5,000,001 - \$10,000,000 | <input type="checkbox"/> |
| Over \$10,000,000 | <input type="checkbox"/> |
| Cost Savings Other | <input type="checkbox"/> |

Cost Savings Comments

The utilization of Medical Devices Advisory Committee enables the Agency to obtain required and frequently scarce professional services from medical and scientific experts not otherwise available to the Agency; and to obtain the services of these experts only on an as needed basis rather than on a full time basis. The services of the Committee resulted in advice for the improvement of the public health for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?

301

Number of Recommendations Comments

The Committee made 301 recommendations from FY03 through FY18---See question 20a of the annual report or specific accomplishments.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

80%

% of Recommendations Fully Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?

10%

% of Recommendations Partially Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☒ No ☐ Not Applicable ☐

Agency Feedback Comments

It usually does. Product approval issues are first released to the sponsor. When appropriate information is made available to the public. Actions related to guidance documents or other general matters issues are available publicly when implemented.

What other actions has the agency taken as a result of the committee's advice or recommendation?

Checked if Applies

Reorganized Priorities	<input checked="" type="checkbox"/>
Reallocated resources	<input type="checkbox"/>
Issued new regulation	<input checked="" type="checkbox"/>
Proposed legislation	<input type="checkbox"/>
Approved grants or other payments	<input type="checkbox"/>
Other	<input checked="" type="checkbox"/>

Action Comments

FDA approves or chooses not to approve an investigational new medical product.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

Checked if Applies

Contact DFO	<input checked="" type="checkbox"/>
Online Agency Web Site	<input checked="" type="checkbox"/>
Online Committee Web Site	<input type="checkbox"/>
Online GSA FACA Web Site	<input checked="" type="checkbox"/>
Publications	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

Access Comments

N/A